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Our Docket No. PDC 116
Your Docket No. **Client/Matter No.** 078374/00002

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MESSAGE:

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellants: Solomon S. Steiner, Robert Feldstein, Per B. Fog, and Trent Poole

Serial No.: 09/621,092 Art Unit: 3743

Filed: July 21, 2000 Examiner: M. Patel

For: *UNIT DOSE CAPSULES AND DRY POWDER INHALER*

SUBSTITUTE APPEAL BRIEF
TRANSMITTAL FORM PTO/SB/21
FEE TRANSMITTAL FORM PTO/SB/17

(45054795.1)

PTO/SB/21 (09-04)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission: 17

Application Number	09/621,092
Filing Date	July 21, 2000
First Named Inventor	Steiner et al.
Art Unit	3743
Examiner Name	M. Patel
Attorney Docket Number	PDC 116

ENCLOSURES *(Check all that apply)*

- ☑ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
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- ☐ After Allowance Communication to TC
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- ☑ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☐ Other Enclosure(s) (please identify below):

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Pabst Patent Group LLP		
Signature	Rivka D. Monheit		
Printed name	Rivka D. Monheit		
Date	February 23, 2005	Reg. No.	48,731

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Effective on 12/03/2004.
Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

FEE TRANSMITTAL For FY 2005

☑ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT	($) 0.00

Complete if Known	
Application Number	09/621,092
Filing Date	July 21, 2000
First Named Inventor	Steiner et al.
Examiner Name	M. Patel
Art Unit	3743
Attorney Docket No.	PDC 116

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FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

Application Type	FILING FEES Fee ($)	FILING FEES Small Entity Fee ($)	SEARCH FEES Fee ($)	SEARCH FEES Small Entity Fee ($)	EXAMINATION FEES Fee ($)	EXAMINATION FEES Small Entity Fee ($)	Fees Paid ($)
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	Fee ($)	Small Entity Fee ($)
Each claim over 20 or, for Reissues, each claim over 20 and more than in the original patent	50	25
Each independent claim over 3 or, for Reissues, each independent claim more than in the original patent	200	100
Multiple dependent claims	360	180

Total Claims	Extra Claims	Fee ($)	Fee Paid ($)	Multiple Dependent Claims Fee ($)	Multiple Dependent Claims Fee Paid ($)
7 - 20 or HP =	0 x	_____	= _____	_____	_____

HP = highest number of total claims paid for, if greater than 20

Indep. Claims	Extra Claims	Fee ($)	Fee Paid ($)
1 - 3 or HP =	0 x	_____	= _____

HP = highest number of independent claims paid for, if greater than 3

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee ($)	Fee Paid ($)
_____ - 100 =	_____ / 50 =	_____ (round up to a whole number)	x _____	= _____

4. OTHER FEE(S)

	Fees Paid ($)
Non-English Specification, $130 fee (no small entity discount)	
Other: _____	

SUBMITTED BY

Signature	Rivka D. Monheit	Registration No. (Attorney/Agent) 48,731	Telephone (404) 879-2152
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellants: Solomon S. Steiner, Robert Feldstein, Per B. Fog, and Trent Poole

Serial No.: 09/621,092 Art Unit: 3743

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Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUBSTITUTE APPEAL BRIEF

Sir:

Responsive to the Notification of Non-Compliant Appeal Brief under 37 C.F.R. § 41.37 mailed on February 17, 2004, this is a substitute Appeal Brief to replace the Appeal Brief filed on November 9, 2004. This is an appeal from the final rejection of claims 30, 41, and 43-45 in the Office Action mailed April 8, 2004, in the above-identified patent application. A Notice of Appeal was filed on August 9, 2004. A Petition for Extension of Time to extend the period for response one month, to and including November 9, 2004 was submitted with the Appeal Brief filed on November 9, 2004. In the Appeal Brief filed November 9, 2004, the Commissioner was authorized to charge $225.00 to Deposit Account No. 50-3129, the sum of the fee for a small entity for filing an Appeal Brief ($170.00) and the fee for a one-month extension of time for a small entity ($55.00). It is believed that no additional fee is required with this submission.

However, should an additional fee be required, the Commissioner is hereby authorized to charge the fee to Deposit Account No. 50-3129.

(1) REAL PARTY IN INTEREST

The real party in interest of this application is MannKind Corp., the assignee.

(2) RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences known to appellant, the undersigned, or appellant's assignee which directly affects, which would be directly affected by, or which would have a bearing on the Board's decision in this appeal.

(3) STATUS OF CLAIMS

Claims 28-30, 41, and 43-45 are pending. Claims 1-27, 31-40, and 42 have been cancelled. Claims 28 and 29 have been objected to for depending from a rejected base claim. Claims 30, 41, and 43-45 are on appeal. The text of each claim on appeal, as pending, is set forth in an Appendix to this Appeal Brief.

(4) STATUS OF AMENDMENTS

The claims were last amended in the Response and Amendment filed via facsimile transmission on January 21, 2004.

(5) SUMMARY OF CLAIMED SUBJECT MATTER

Capsules containing drug which is administered using an inhaler have been modified to include at least one keying surface on an outside surface of a distal end of the capsule that is either (1) adapted to orient the capsule within the inhaler and/or (2) identify the drug in the capsule (page 11, lines 14-24 and Figure 7). At least one hole in the capsule allows air to enter

into the capsule and, carrying the drug to be administered, exit the capsule (page 10, lines 4-15). In one embodiment, the capsule contains a keying surface on the outside of one end, which is adapted to orient the capsule within the inhaler, and a keying surface on the outside of the other end, which identifies the drug to be placed in the capsule (Figure 7). The capsule may contain a liquid, powder, or gaseous drug (page 10, line 28 until page 11, line 4 and original claim 30).

The capsules may have different forms. In one embodiment where the capsule is formed of two tubes one partially within the other, the capsule consists of a first tube and a second tube, where the first and second tubes each have a long axis, with an inner and an outer surface radial to the long axis (page 9, lines 25-28). The tube is open at one end perpendicular to the long axis and closed at one end perpendicular to the long axis (page 9, line 27). The first tube has at least one protrusion on its outer surface, while the second tube has at least one protrusion on its inner surface (page 9, line 30 until page 10, line 1). The outer circumference of the first tube is approximately equal to the inner circumference of the second tube, such that the open end of the first tube can slide snugly into the open end of the second tube (page 9, line 24 until page 10, line 2). A protrusion on the outer surface of the first tube may slide past a protrusion on the inner surface of the second tube, locking the tubes together (page 10, lines 1-2). The first and second tubes may each have one or more secondary holes other than the openings at the end of each tube, where at least one secondary hole in the first tube may be made coincident with at least one secondary hole in the second tube when the first tube is slid onto the second tube in the unlocked position by rotation of the first and second tubes about their long axes (page 10, lines 4- 7and 10-14). When the first tube is locked onto the second tube, at least two secondary holes in the first

tube may be made coincident with at least two secondary holes in the second tube by rotation of the first and second tubes about their long axes (page 10, lines 7-8). In a further embodiment, the first and second tubes of this capsule contain keying surfaces at the closed ends of the tubes (page 11, lines 14-16).

(6) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The sole issue presented on appeal is whether claims 30, 41 and 43-45 are novel as required by 35 U.S.C. § 102(b) over U.S. Patent No. 4,991,605 to Keritsis ("Keritsis").

(7) GROUPING OF CLAIMS

The claims do not stand or fall together. Reasons for this grouping and arguments for the separate patentability of these groups of claims are provided below.

(8) ARGUMENT

i. The Claimed Capsule

Inhalers are used to deliver drug to the pulmonary region of a patient. The drug is typically provided in a single dosage form, such as a blister pack or capsule. Many patients, especially diabetics, have trouble readily identifying and inserting capsules within an inhaler due to age, poor eyesight, and lack of fine motor control. In response to this need, appellants developed an improved capsule for administration to patients using an inhaler. Keying surfaces are used to ensure that the capsule is properly aligned in the inhaler and/or to uniquely identify the drug that is inside of the capsule. The keying surface must be properly aligned within the inhaler for the capsule to be fully inserted and the cap closed so that the drug can be administered. This is particularly important where the mechanism for delivering the drug is

inhalation, which pulls air from a port in the inhaler through a first hole at the bottom of the capsule and up and out of the top of the capsule and into the patient's oral cavity. If the capsule is not properly aligned, the holes will not line up with the air intake port and there will be insufficient air force to deliver the full dosage to the patient (see page 11, lines 8-18 and Figures 7 and 18). The keying surfaces may have different shapes which allow the capsule to mate with the inhaler (see page 11, lines 8-15) and which have unique identifying features. Many diabetics have impaired eyesight. They also tend to take a variety of medicines. It is difficult for them to read small labels. With a keyed surface, the patient is able to identify the capsule by the key which is specific for the drug. The inhaler has features that prevent the wrong drug from being administered since only if the alignment key and the identification key are correct can the cap be closed on the inhaler. This also prevents the capsule from being inserted upside down.

ii. Rejection Under 35 U.S.C. § 102

Legal Standard

The standard for lack of anticipation is one of strict identity. To anticipate a claim for a patent, a single prior source must contain all of the claimed elements. Federal Circuit decisions repeatedly emphasize that anticipation is established only if the following three standards are met: (1) all the elements of an invention, as stated in a patent claim, (2) are identically set forth, (3) in a single prior art reference. *See e.g. Transclean Corp. v. Bridgewood Services, Inc.*, 290 F.3d 1364, 62 USPQ2d 1865 (Fed. Cir. 2002); *EMI Group North America, Inc. v. Cypress Semiconductor Corp.*, 268 F.3d 1342, 1350, 60 U.S.P.Q.2d 1423 (Fed. Cir. 2001) ("A prior art reference anticipates a patent claim if the reference discloses, either expressly or inherently, all

of the limitations of the claim."); *Acromed Corp. v. Sofamor Danek Group, Inc.*, 253 F.3d 1371, 1383, 59 U.S.P.Q.2d 1130 (Fed. Cir. 2001) ("Normally, to invalidate a patent by anticipation a prior art reference needs to disclose each and every limitation of the claim."); *Eli Lilly & Co. v. Barr Laboratories, Inc.*, 251 F.3d 955, 970, 58 U.S.P.Q.2d 1865 (Fed. Cir. 2001) ("A reference is anticipatory if it discloses every limitation of the claimed invention either explicitly or inherently."). To constitute an anticipation, a printed publication must describe the claimed invention with sufficient detail to enable a person of ordinary skill in the art to make it. *See* 1 Chisum on Patents § 3.04 [1] (1978 & rev. 2004).

Keritsis does not disclose all of the limitations in claims 30, 41 and 43-45

Keritsis does not disclose capsules for delivery of drug using an inhaler. Keritsis does not disclose a capsule for delivery of a drug using an inhaler having at least one hole for directing air through the capsule. On this basis alone, Keritsis does not disclose every element of the claimed devices.

More importantly, however, Keritsis does not disclose a keying surface on an outside surface of a distal end of the capsule, as required by claim 41 and its dependent claims. Keritsis describes smoking containers for adding flavorants and other additives that modify the characteristic of cigarettes and other smoking articles (see col. 7, lines 62-65). One container is depicted in Figures 6, 6A and 7. As illustrated in Figure 6, elements 610, 620 and 630 are combined to form the container that holds the additive. The specification explains that "element 610 is open at one end and closed at the other end by surface 616" (see col. 5, lines 65-66). Thus, element 610 alone cannot be characterized as a "capsule". There is no motivation to

modify what is disclosed to form a capsule as claimed. Even if the combination of 610, 620 and 630 could be characterized as a "capsule", this capsule does not contain a keying element, let alone one that is located at the distal end of the capsule.

Element 613 is a ridge which allows element 610 to slide inside element 620 along the surface of element 623. Elements 613 and 623 run along the full length of their respective tubes, thus they are not located at the *distal end* of the capsule. Further, the combination of both elements 610 and 620, forms the complete capsule (see Figure 6). Thus, neither surface 613 nor 623 is located on an *outside surface* of the capsule. Similarly, element 619 is a smooth surface at an open end of one of the tubes. As noted in col. 6, lines 6-10, element 619 "is configured to fit *inside* lip 622 of element 620" (emphasis added). Thus, element 619 is located *inside* the capsule. Thus, none of the elements cited by the Examiner are keying surfaces located on an *outside* surface of a distal end of the capsule, as required by claims 30, 41, and 43-45.

Further, even if element 610 was considered to be a "capsule", it lacks one or more keying surfaces on its distal ends. As noted above, element 613 runs along the full length of element 610. It is not located on the end of element 610. In contrast, as described in Appellants' specification and depicted in Figures 7 and 18, the keying surfaces are located on opposite ends of the capsule. Therefore claims 30, 41, and 43-45 are novel over Keritsis.

Claims 43 and 45 are novel over Keritsis

In addition the failure of Keritsis to disclose the elements of independent claim 41, discussed above, Keritsis does not disclose a keying surface that orients the capsule within an inhaler, as required by claims 43 and 45. Keritsis discloses that the container should be located

in the "smoke" stream of the smoking article and that the container may be held in place by wrapping it with an overwrapper or tipping paper (col. 2, lines 26-40). Thus, Keritsis does not disclose a capsule that is capable of orienting itself within an inhaler. Rather, Keritsis requires a wrapper to keep the smoking article and smoking container connected to each other and oriented in the desired position. Therefore claims 43 and 45 are novel over Keritsis.

Claims 44 and 45 are novel over Keritsis

In addition to failure of Keritsis to discloses a capsule for use in an inhaler, at least one hole in the capsule that allows air to disperse and deliver the drug within the capsule to a patient, Keritsis does not disclose how or where one would place an identifier for the drug to be placed in the capsule, as required by claims 44 and 45. Further, as noted below, Keritsis does not even disclose including a medicament in the capsule. Therefore claims 44 and 45 are novel over Keritsis.

Claim 30 is novel over Keritsis

The failure of Keritsis to disclose the features of the capsule of the independent claims is discussed above. Keritsis also does not disclose including a medicament in the capsule, as required by claim 30. Keritsis includes flavorants and other additives that modify the characteristic of cigarettes and other smoking articles (see col. 7, line 62 until col. 8, line 8). A medicament is defined as "an agent that promotes recovery from injury or ailment; a medicine." (*See* enclosed printout from The American Heritage® Dictionary of the English Language (4th Ed.) (2000)). The additives in Keritsis's capsule add taste or flavor to the cigarette. They do not promote recovery from an injury or ailment. Thus, claim 30 is novel over Keritsis.

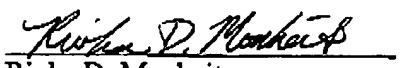
(9) SUMMARY AND CONCLUSION

Keritsis does not disclose all of the elements of the claimed capsules as required under 35 U.S.C. § 102. Keritsis does not disclose a capsule for use in an inhaler. Keritsis does not disclose a keying surface at the distal end of the capsule, nor on the outside surface of the capsule, which can be used to orient the capsule in an inhaler, nor a keying surface to uniquely identify the drug within the capsule. Additionally Keritsis requires wrapping paper to attach the smoking container to the smoking device. Keritsis includes taste modifying additives in the capsule, not medicaments. Finally, Keritsis does not disclose that an identifying marker should be placed on the smoking container, let alone one which identifies a drug to be placed in the capsule. Therefore, claims 30, 41, and 43-45 are novel over Keritsis.

Although not raised by the examiner, it is equally clear that Keritsis cannot make obvious the claimed subject matter, since there is no recognition of the claimed elements, alone or in combination, with motivation to combine as appellants have done, since there is no disclosure of an inhaler, much less a capsule for use therein.

For the foregoing reasons, Appellant submits that claims 28-30, 41, and 43-45 are patentable.

Respectfully submitted,



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Claims Appendix: Claims On Appeal

28. (previously presented) The capsule of claim 41 comprising a first tube and a second tube, wherein:

(a) a first tube having a long axis, having an inner and an outer surface radial to the long axis, wherein the tube is open at one end perpendicular to the long axis and closed at one end perpendicular to the long axis; and wherein the first tube has at least one protrusion on its outer surface; and

(b) a second tube having a long axis, having an inner and an outer surface radial to the long axis, wherein the tube is open at one end perpendicular to the long axis and closed at one end perpendicular to the long axis and wherein the second tube has at least one protrusion on its inner surface; and wherein the outer circumference of the first tube is approximately equal to the inner circumference of the second tube, such that the open end of the first tube can slide snugly into the open end of the second tube; and wherein a protrusion on the outer surface of the first tube may slide past a protrusion on the inner surface of the second tube, locking the tubes together;

and wherein the first tube and the second tube each have one or more secondary holes other than the openings at the end of each tube, wherein at least one secondary hole in the first tube may be made coincident with at least one secondary hole in the second tube when the first tube is slid onto the second tube in the unlocked position by rotation of the first and second tubes about their long axes, and

wherein when the first tube is locked onto the second tube at least two secondary holes in the first tube may be made coincident with at least two secondary holes in the second tube by rotation of the first and second tubes about their long axes.

29. (original) The capsule of claim 28 wherein the first and second tubes further comprise keying surfaces at the closed ends of the tubes.

30. (previously presented) The capsule of claim 41 further including medicament selected from the group consisting of liquid, powder, and gaseous medicaments.

41. (previously presented) A capsule to contain drug for use in an inhaler comprising at least one keying surface on an outside surface of a distal end of the capsule that is adapted to orient the capsule within the inhaler or identifies the drug to be placed in the capsule and

at least one hole allowing air to pass in, through and out of the capsule.

43. (previously presented) The capsule of claim 41 wherein the keying surface is adapted to orient the capsule within the inhaler.

44. (previously presented) The capsule of claim 41 wherein the keying surface identifies the drug to be placed in the capsule.

45. (previously presented) The capsule of claim 41 comprising a keying surface on the outside of one end which is adapted to orient the capsule within the inhaler and a keying surface on the outside of the other end which identifies the drug to be placed in the capsule.

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Evidence Appendix:

"medicament", The American Heritage® Dictionary of the English Language (4th Ed.) (2000)